VA MEDICAL CENTER, PORTLAND, OREGON
Human Research Protection Program: Policy & Procedure No. 7

POLICY for DETERMINATION of INSTITUTIONAL REVIEW BOARD REVIEW of CASE REPORTS and RETROSPECTIVE CHART REVIEWS

1. **PURPOSE:** To establish a service level policy that defines a case report and retrospective chart review and identifies when a case report must receive Institutional Review Board (IRB) and Research & Development (R&D) review and approval at the Portland VA Medical Center.

2. **POLICY:** All individuals conducting case reports must abide by the terms of this policy. Prior to conducting a case report, a clinician must submit a completed Application for Case Report Review to the IRB Coordinator to ensure compliance with this policy and the Health Information Portability and Accounting Act (HIPAA). Case reports produced by a clinician, regarding three or less patients for whom the clinician has personally provided care, generally does not need IRB and R&D Committee approval. Case reports that satisfy all of the four following criteria are not considered research and do not require IRB and R&D Committee approval. The four necessary criteria include:
   a. case reports of patients, which have been produced by a clinician that has personally provided care for those patients;
   b. case reports consisting of three or fewer patients;
   c. case reports that are an account of an observation or a description of the disease process;
   d. case reports that are not presented as a systematic investigation, including either statistical or systematic qualitative analysis, designed to contribute to generalizable knowledge.

   If a case report does not satisfy all of the four criteria, IRB and R&D Committee review and approval must be sought.

3. **DEFINITIONS:**
   a. **Research:** Research is defined as an activity designed to develop or contribute to new generalizable knowledge through a process of hypothesis testing and data collection that permits conclusions to be drawn. Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective. Any prospective or retrospective collection of clinical data with the intent to contribute to generalizable knowledge constitutes human studies research. Examples of such clinical data collection include research seminars, posters, abstracts, and manuscripts.

      Local medical center and affiliated institutional conferences for teaching, quality assurance or quality improvement activities, and patient care activities (for example, ward rounds, case conferences, departmental seminars, morbidity & mortality conferences, X-ray conferences, tumor boards) are specifically not considered as research by this definition.
   b. **Case Report:** an account of an observation or a description of a disease process, noting three or fewer patients which are those of the clinician preparing the report and are not presented as a systematic investigation designed to contribute to generalizable knowledge.
   c. **Retrospective Chart Review:** a retrospective review of medical charts for publication that does not meet the criteria of 5.a or 5.c below implies research
   d. **VHA Investigator:** A VHA investigator must be a VHA employee (which includes official Without Compensation (WOC) employees) or contract personnel. Reference: VHA Handbook 1605.1, December 31, 2002.

4. **RESPONSIBILITIES:**
   a. The **Associate Chief of Staff of Research & Development** is responsible for developing and managing policies and procedures regarding the determination of IRB and R&D Committee review and approval for case report(s).

   b. The **Research & Development Committee** (R&D) is responsible for reviewing case reports when a case report does not satisfy the four criteria stated in the policy section above.

c. The **Institutional Review Board** (IRB) is responsible for reviewing case reports when a case report does not satisfy the four criteria stated in the policy section above.

d. The **Institutional Review Board** (IRB) **Coordinator** is responsible for reviewing Application for Case Report Reviews and determining whether or not the HIPAA regulations have been satisfied and whether or not IRB and R&D Committee approval is necessary.

e. **Principal Investigators**
Principal Investigators (VHA Investigator) who conduct case reports are responsible for:
(1) Submitting an Application for Case Report Review to the Grants Program Specialist, prior to conducting a case report;
(2) Complying with the determination of the Grants Program Specialist, regarding the appropriateness of conducting a case report;
(3) Ensuring that individually identifiable information (protected health information) is excluded from the published case report;
(4) Conducting case reports only of patients for whom they have personally provided care or seek prospective IRB and R&D Committee approval.
(5) Submitting the appropriate prospective IRB application for conducting case reports when the case report does not meet the four necessary criteria stated in the policy section above.

f. **Medical Center Staff and Residents**
Medical Center Staff who conduct case reports are responsible for:
(1) Submitting an Application for Case Report Review to the Grants Program Specialist, prior to conducting a case report;
(2) Complying with the determination of the Grants Program Specialist, regarding the appropriateness of conducting a case report;
(3) Ensuring that individually identifiable information (protected health information) is excluded from the published case report;
(4) Conducting case reports only of patients, for whom at least one author has personally provided care or seek prospective IRB and R&D Committee approval.
(5) Submitting the appropriate prospective IRB application for conducting case reports when the case report does not meet the four necessary criteria stated in the policy section above.

5. **PROCEDURES:**
a. **Case Report: any clinician conducting a case report must adhere to the following procedures:**
(1) The clinician must submit an Application for Case Report Review to the Grants Program Specialist, prior to conducting a case report;
(2) The clinician must be a clinician who has personally provided care to the patients about whom the case reports are written.
(3) If the case report involves the use of photographs that may possible identify the patient, then written permission from the patient is required, prior to any presentation of the photographs.
(4) The case report(s) must meet the following criteria:
(a) The presentation of the case report is to emphasize a particular instance of disease and/or
(b) The case report must be account of an observation or a description of the disease process.
(5) The case report(s) should not be presented as:
(a) a systematic investigation designed to contribute to generalizable knowledge, nor
(b) a systematic qualitative or statistical analysis.

(6) If the Grants Program Specialist determines that the Application for Case Report Review meets that criteria for a case report, IRB and R&D Committee approval is not needed.

b. **Case Report: any clinician conducting a case report consisting of any of the following criteria must receive prospective IRB and R&D Committee approval:**
(1) A case report regarding patients, whom are not patients for which the clinician has personally provided care.
(2) A case report regarding more than three patients, regardless of whether the individual is a clinician that has personally provided care for the patients.
(3) A case report that is presented as a systematic investigation designed to contribute to generalizable knowledge.
(4) A case report that is presented as a systematic qualitative or statistical analysis.

c. **Retrospective Chart Review: any individual conducting a retrospective review of medical charts for the following purposes does not require prospective IRB and R&D Committee approval:**
(1) An investigative review, e.g. to review a physician's competency;
(2) Quality management issues, e.g. to ascertain delivery of health care needs;
(3) Compliance issues, e.g. in relationship to third party billing, or investigation of non-compliance.
(4) A review to obtain clinical information for teaching purposes.

d. **Retrospective Chart Review: any individual conducting a retrospective review of medical charts for publication that does not meet the criteria of 5.a or 5.c above implies research and therefore requires prospective IRB and R&D Committee approval.** The individual must follow the following procedures:
(1) Write a protocol
(a) Describe the research question
(b) Describe what information will be extracted from the medical record to answer that question
(c) Describe the risks and benefits of the research on the subject(s)
(d) Describe how confidentiality will be maintained
(e) Include a code sheet, if applicable.
(2) Complete the following forms, available from the Research & Development Website: (http://www.visn20.med.va.gov/portlandrd/pages/support/award/form.htm)
(a) Proposed Project Questionnaire (PPQ), which provides background and tracking information to the Research Service
i. Requests an abstract (500 words or less) with the following headings
(i) Objectives
(ii) Plan
(iii) Methods
(b) Initial Review Questionnaire (IRQ), which allows the IRB to focus on the details necessary to provide a thorough review of the project.
(c) Waiver of Informed Consent/Authorization, which the IRB uses to determine if all applicable regulations are satisfied.
(3) Submit all of the items in (1) and (2) above to the Research Service for review by the IRB and R&D Committee.
(4) Once final IRB and R&D Committee approvals are received, the retrospective review of medical records may begin.

6. REFERENCES:
Office of Research Compliance & Assurance Guidance, E-mail 03/10/2003

Office of Human Research Protections Guidance, E-mail 03/10/2003
VHA Handbook 1605.1, December 31, 2003

7. **CONCURRENCES:** Endorsed by the Research & Development Committee May 19, 2003

8. **RESCISSION:** None

9. **FOLLOW-UP RESPONSIBILITY:** ACOS Research & Development Service (R&D)

10. **REVIEW DATE:** May 19, 2004

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